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A61N 1/05

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A5R RHEPV

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(54) Electrical stimulation for treatment of incontinence

(57) Portable electrical stimulation apparatus for treatment of incontinence comprises an electrode for applying electrical pulse signals to a patient's anal or vaginal tract. The electrode is in the form of a tampon with an inner core 100 moulded from resilient and deformable material such as paper or cotton fibre. An outer flexible conductive sheath 101 is of knitted or woven fibre, eg stainless steel or metallised plastics. The sheath 101 is gathered into a thread 102 and connected 103 to a wire conductor 104 coupled to a pulse generator. The sheath 101 may alternatively be in the form of one or more conductive bands.

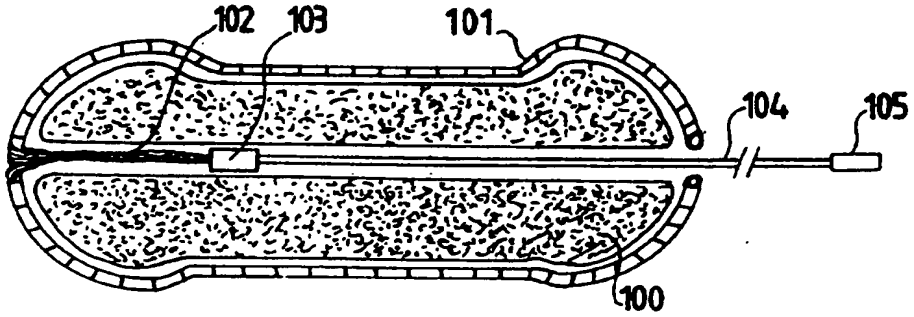

FIG. 27

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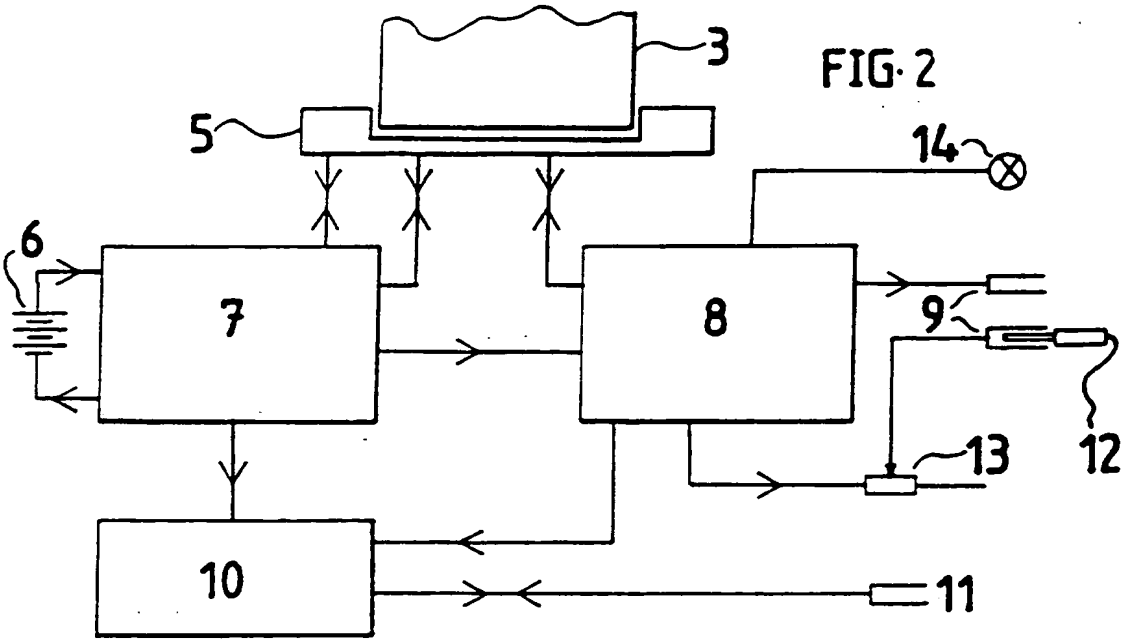
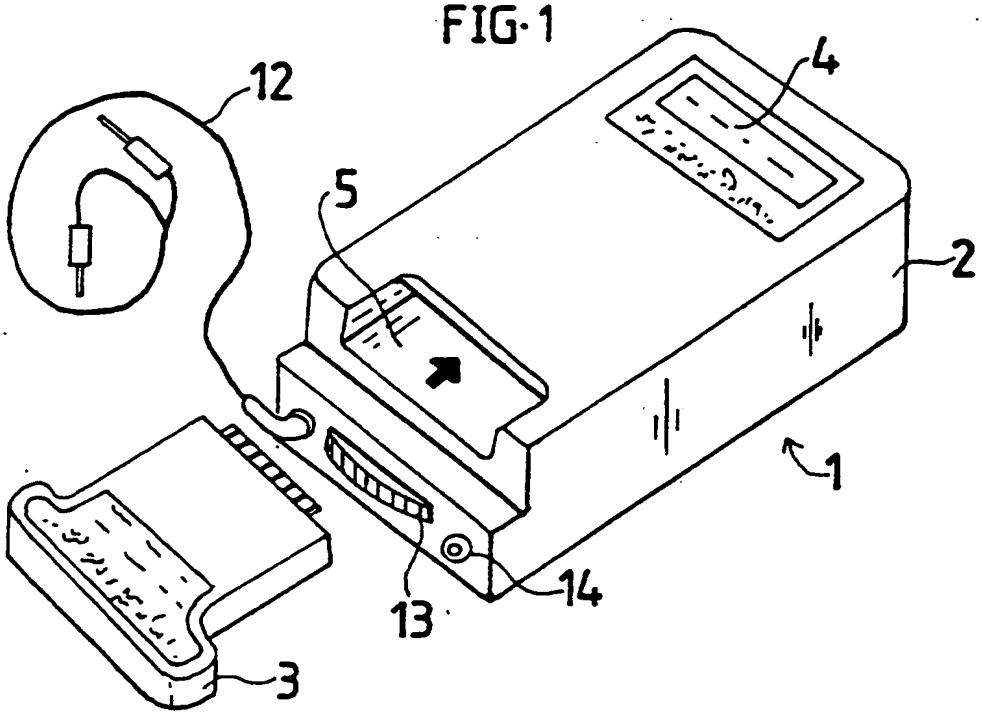
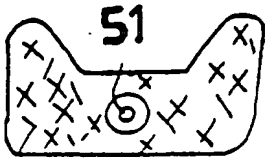
FIG·2



FIG·1





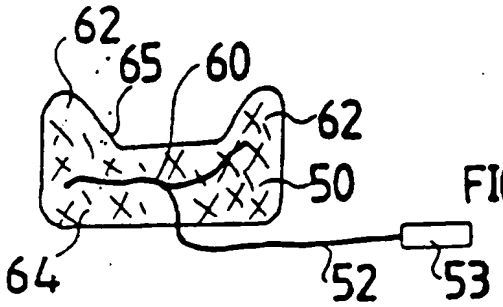
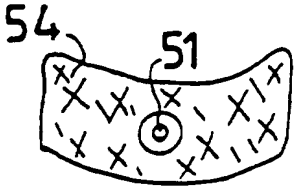


FIG. 3



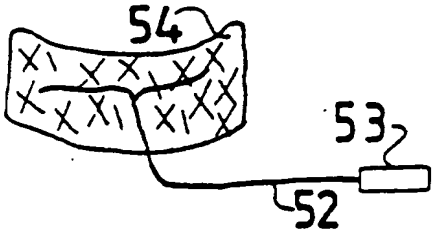
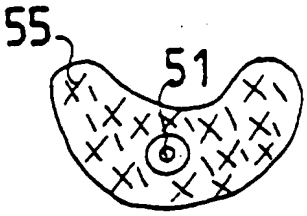


FIG. 4



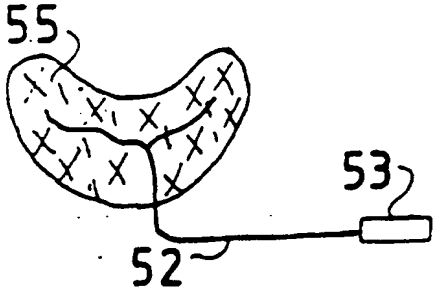


FIG. 5

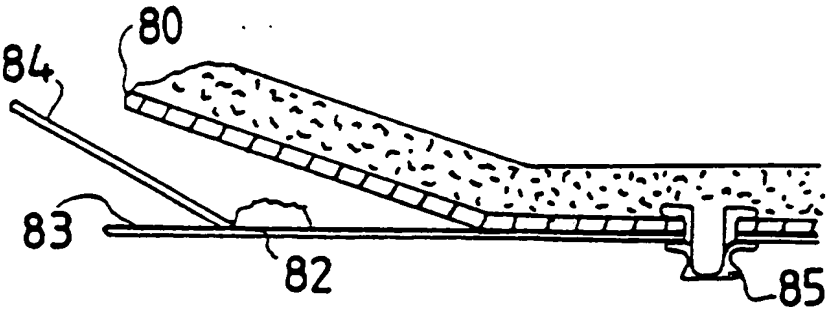


FIG. 8

FIG. 6

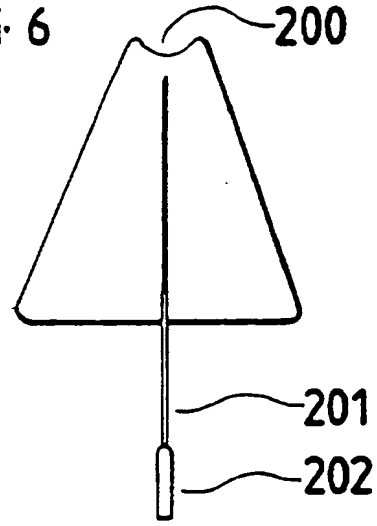


FIG. 7

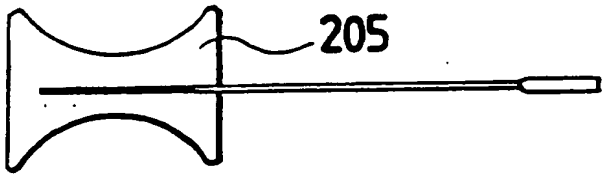


FIG. 9

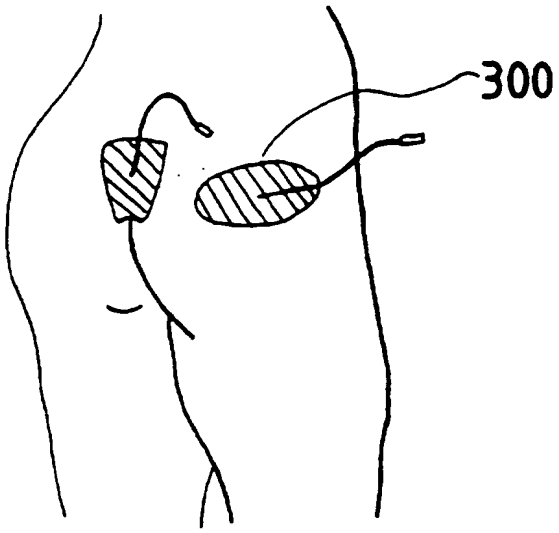
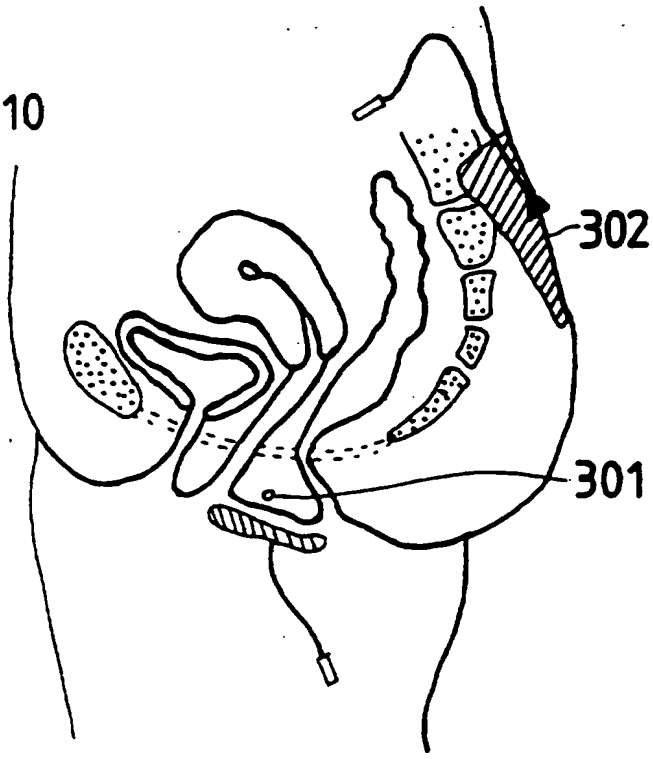


FIG. 10



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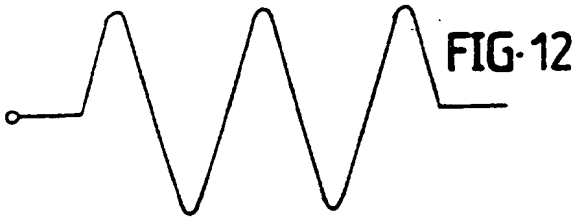


FIG. 12

FIG. 13

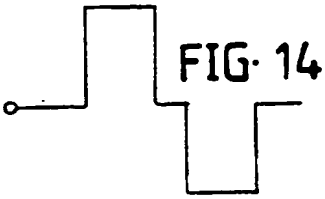


FIG. 14

FIG. 15

FIG. 16

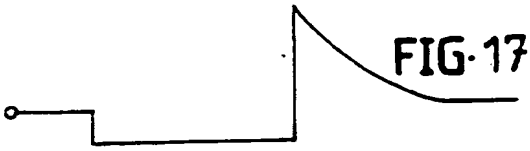
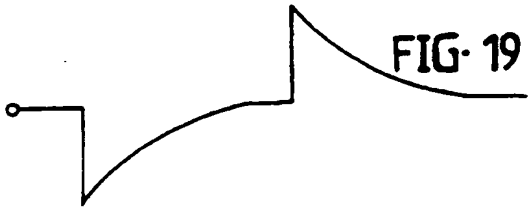


FIG. 17

FIG. 18



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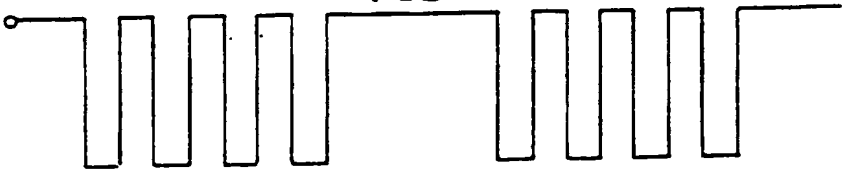
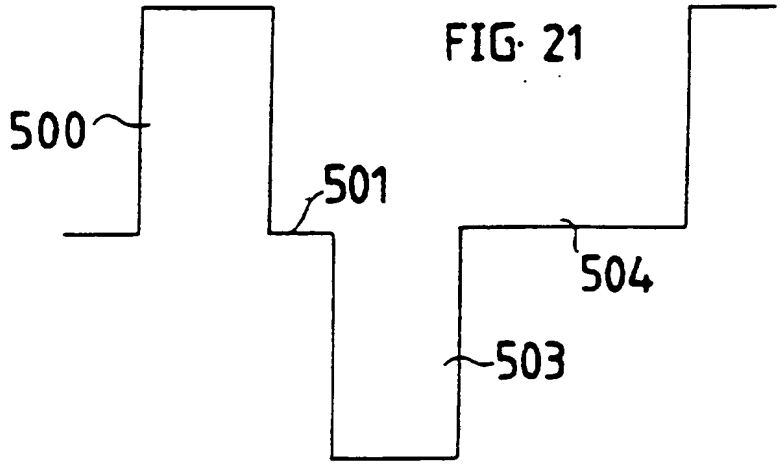


FIG. 20

FIG. 21



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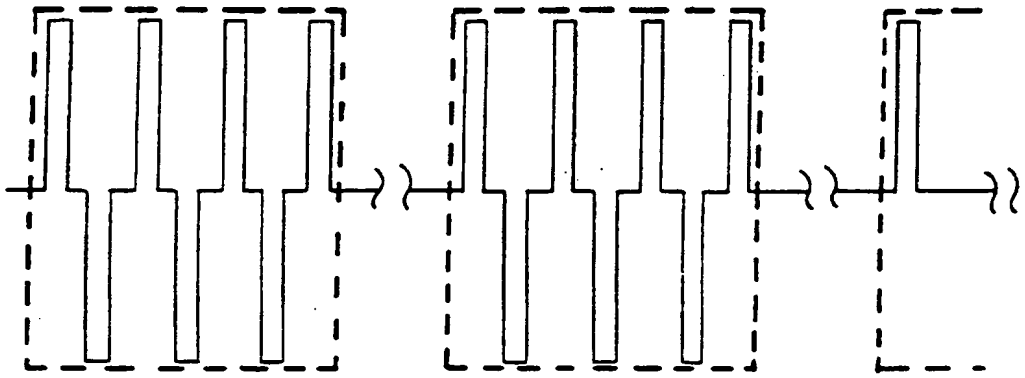

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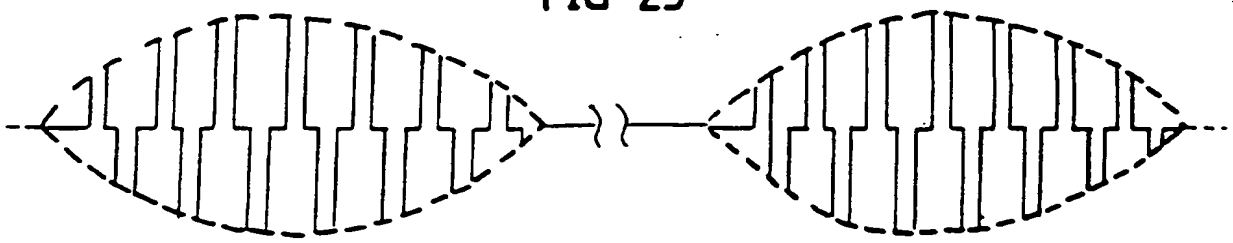

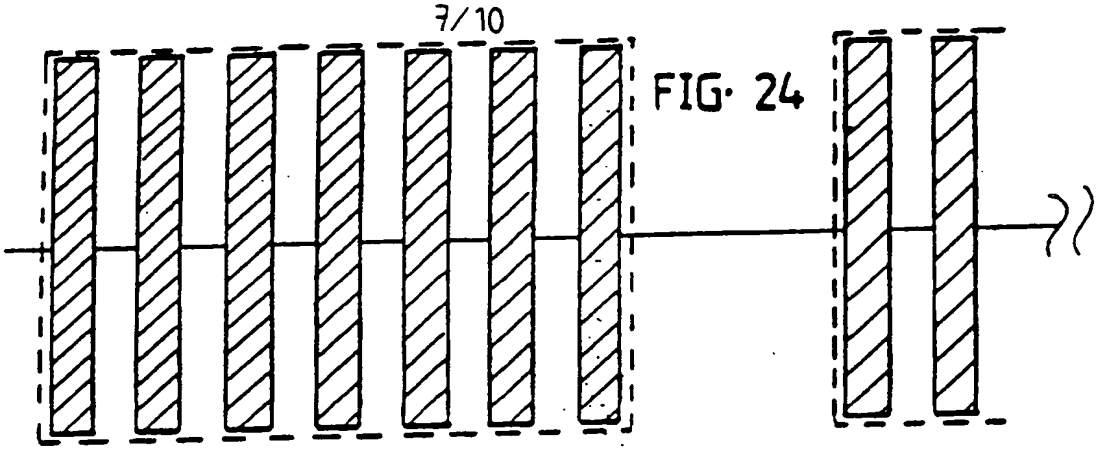

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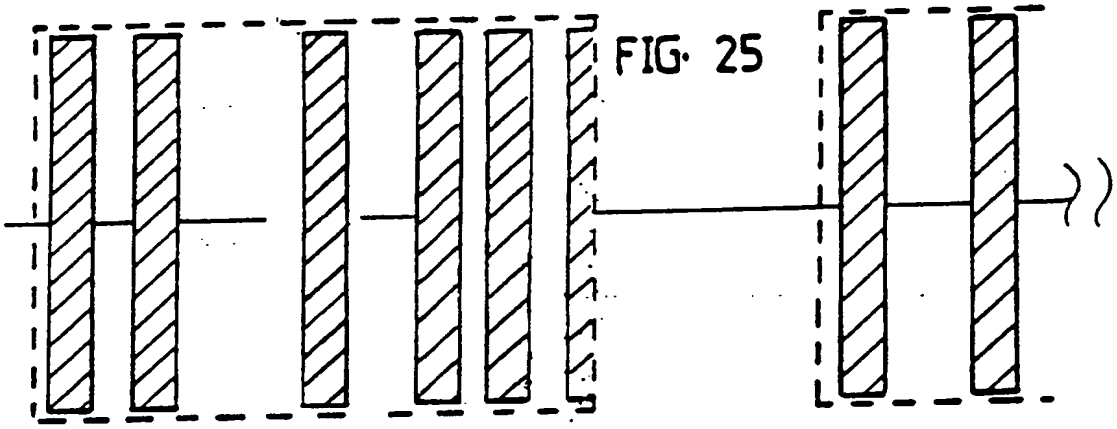

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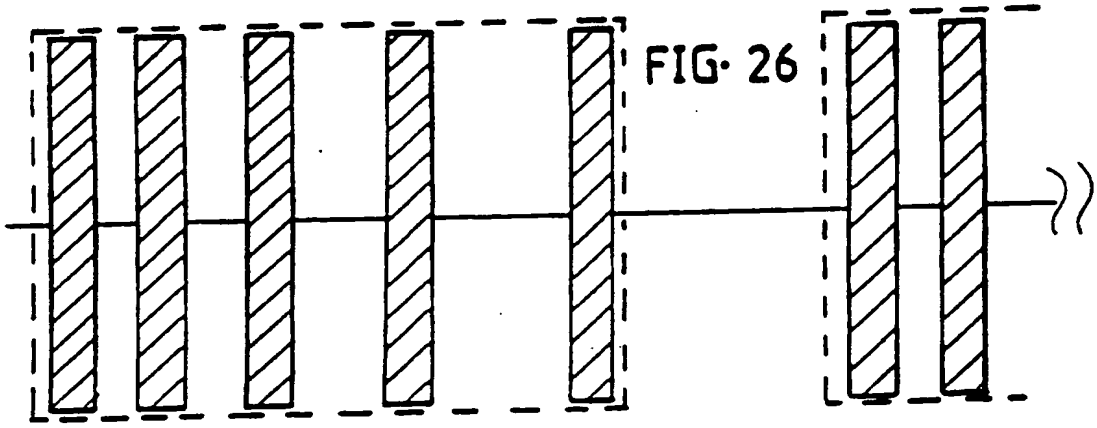


FIG. 26

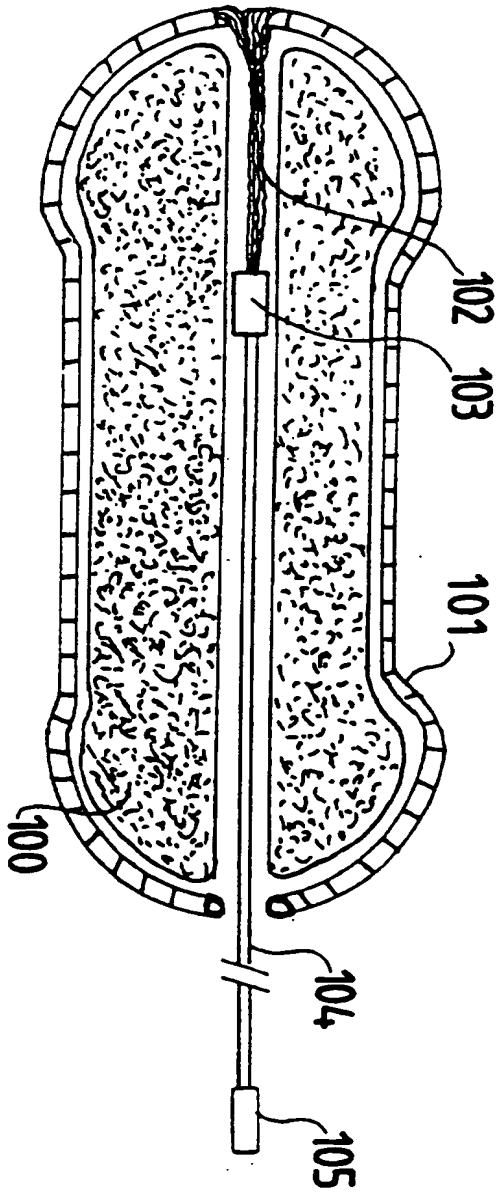
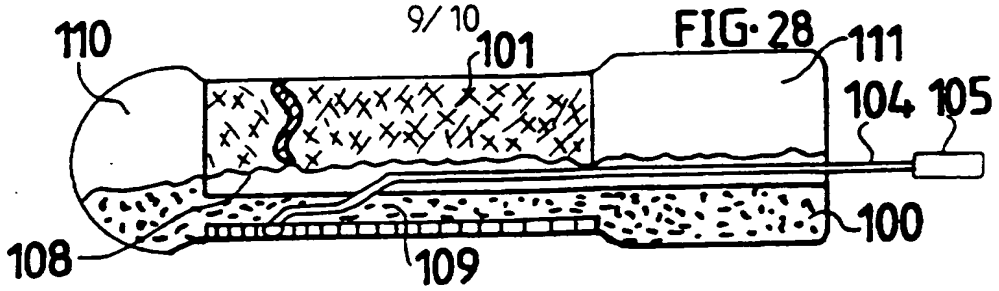
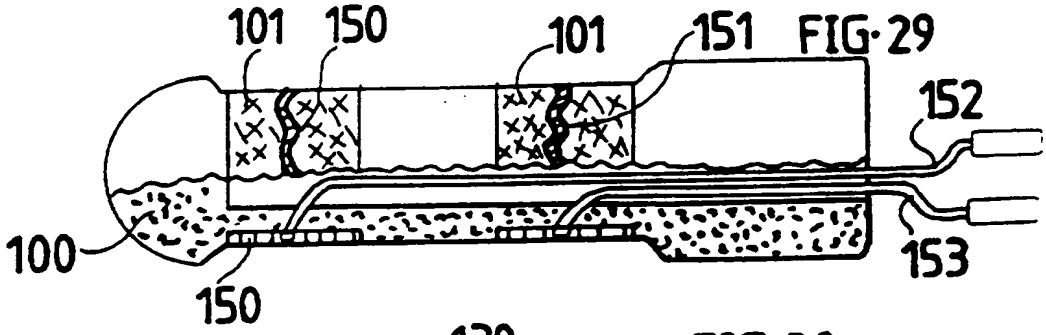


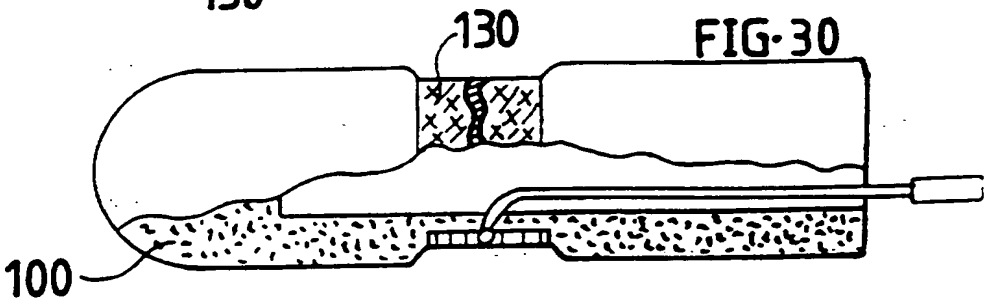
FIG. 27



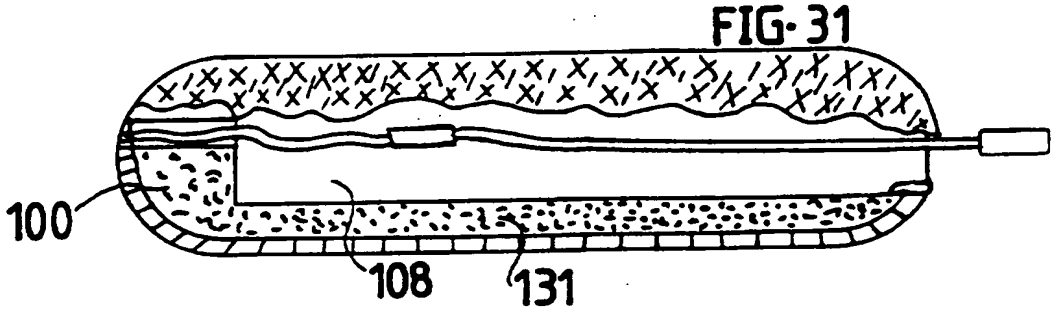
FIG·28



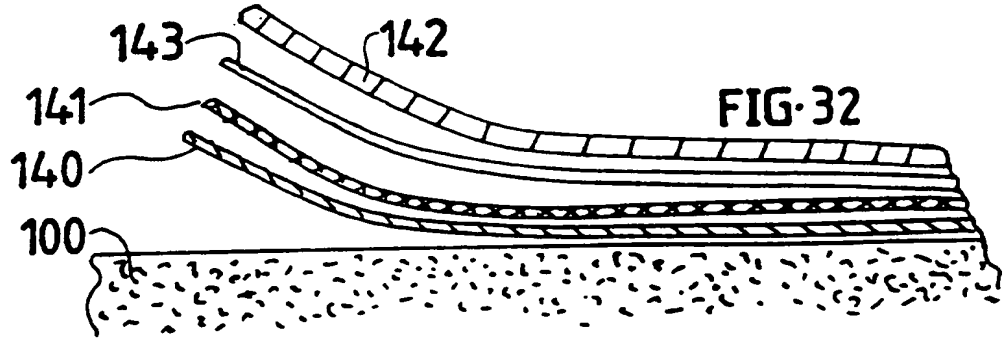
FIG·29



FIG·30



FIG·31



FIG·32

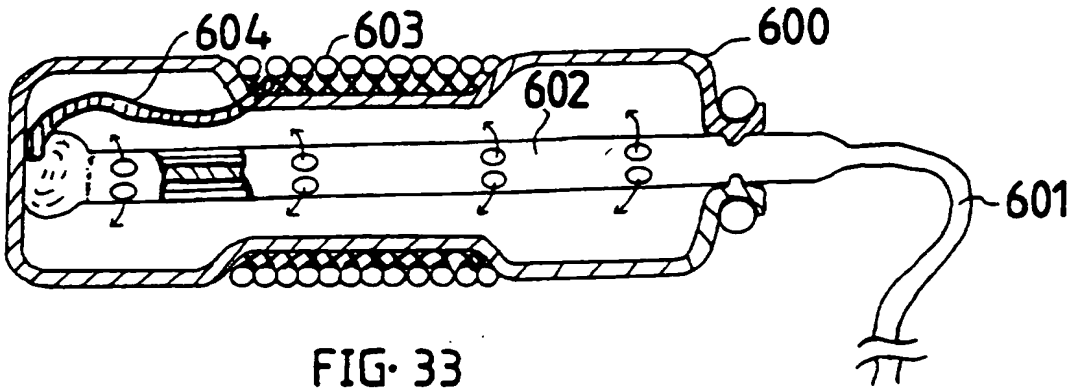


FIG. 33

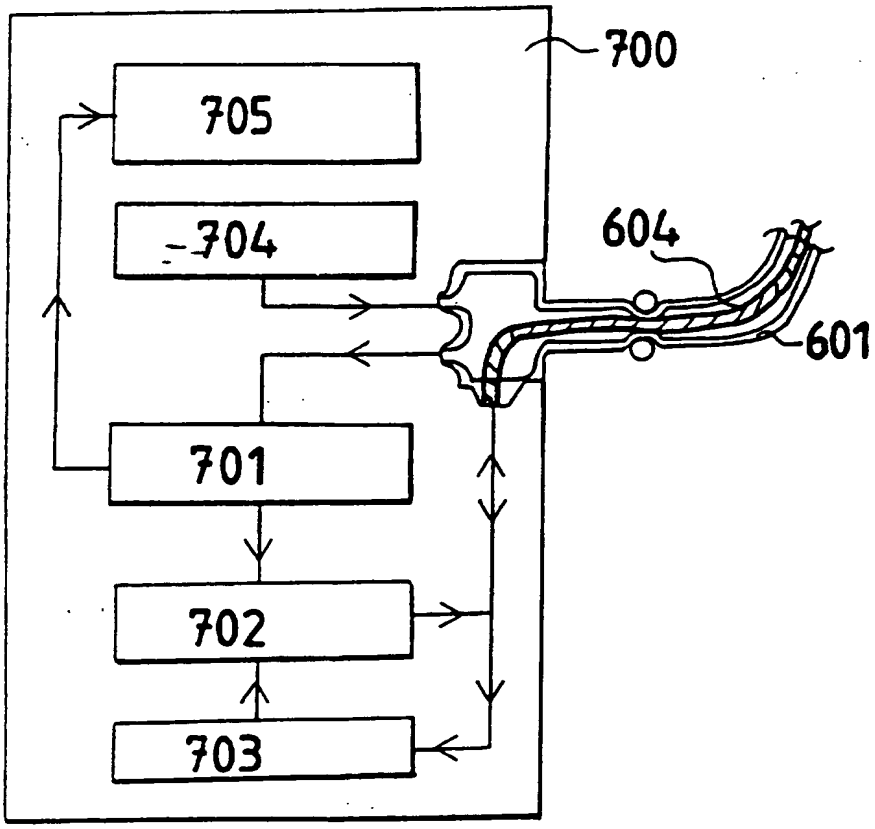


FIG. 34

ELECTRICAL STIMULATION FOR TREATMENT OF INCONTINENCE AND OTHER NEURO-MUSCULAR DISORDERS

Technical Field

The present invention relates to electrical nerve and muscle stimulation and particularly although not exclusively to electro-medical treatment for urinary and faecal incontinence, primarily in women but equally adaptable for men.

Background Art

Conventional electro-stimulation treatments for urinary and faecal incontinence require a patient to apply stimulation via an internal electrode in electrical contact with the body. Treatment is applied for periods ranging from 10 minutes to several hours each day.

A conventional electro-stimulation system includes pulse generator housed in a portable battery box, and an electrode pad for attachment to the patient. Such systems are often used for the relief of chronic back pain or induced muscle contraction. These systems fall under the general classification of transcutaneous electrical nerve stimulation systems (TENS).

The above mentioned electro-stimulation systems conventionally use a drive signal to the electrode which is characterised by a sine wave, square wave, or spike impulse geometry, and is either monophasic, capacitively coupled monophasic, biphasic or asymmetric. Differing therapeutic effects are achieved using different drive signal types. Conventionally such stimulation systems allow for a variation of drive signal pulse width or frequency by the patient. However each such known portable stimulation

system has electronics which are dedicated for providing a specific predetermined drive signal having a geometry and other characteristics matched to the intended therapeutic effect. Adjustment of the control signal is conventionally provided by electronic push switches and or rotational control knobs. Such switches and knobs can often be tampered with by the patient, and it is thus difficult for a medical practitioner prescribing electro-stimulation treatment to control the treatment when the patient is away from a clinic.

Other known electro-stimulators include microprocessor based units, but these have a problem that conventionally, specialised pre-programming equipment needs to be used at the clinic to set the signal parameters. Such equipment is expensive and often difficult to use.

Specific embodiments of the present invention aim to provide electro-stimulation apparatus which can be adjusted and preset by a medical practitioner, medical assistant or clinician without requiring of them electronic or computer literacy, and once set is tamper proof by a patient.

In the treatment of incontinence, it is known to use a vaginal or rectal electrode comprising a moulded plastic plug which is insertable into the body. Such plugs may be rigid, semi-rigid or of the expanding coil type. However, these known internal electrodes are uncomfortable and problematic due to their fixed size, difficulty to insert and poor contact with the body, producing uncomfortable sudden increases in pulse strength. Subsequently, patients dislike such treatments and compliance with the treatment is poor.

Surface electrodes of metal, metallised foil, carbonized rubber and other similar thin conductive plate materials are known. However, such materials are insufficiently flexible and can be problematic causing discomfort, soreness and subsequently poor compliance to treatment. The known surface electrodes are unsuitably shaped and sized, and insufficiently flexible for application over the perineal region adjacent to the vaginal and rectal tracts.

Prior art cloth electrodes are known from US 5.038,796 and US 4,708,149. These electrodes are designed for functional electrical stimulation (FES) and the symptomatic treatment of such afflictions as arthritic pain and back pain.

Pelvic Floor Exercises are a known treatment for exercising muscles which control the urinary function. Such exercises require levator ani muscles to be contracted and relaxed regularly during the course of a day or over a period of many weeks, often months.

A known aid for such exercises comprises a pre-formed core of rigid plastics material. Such aids are provided in a set of graded weights, requiring the (female) patient to insert them into a vaginal tract, and retain them in position. However, this is difficult for many patients, because commonly the smallest available weight available is too heavy, or the size is incorrect. Insertion and renewal of the cores can be problematic.

Another type of known device comprises a foam cushion, which is used to apply pressure at the bladder neck, keeping the bladder neck closed during normal movement and exercise. However, such devices are not intended for,

and are unsuitable for performing Pelvic Floor Exercises. The devices must be softened with water prior to use.

Disclosure of the Invention

Specific embodiments of the present invention aim to address the problems associated with conventional plug type electrodes, and the problems encountered in the treatment of incontinence.

Specific embodiments of the present invention aim to provide an improved Pelvic Floor Exercise apparatus.

According to the invention there is provided an apparatus for application of electrical stimulation to patients suffering from incontinence, said apparatus comprising:

generator for providing a series of electrical stimulation pulses; and

a tampon electrode means, responsive to said series of electrical stimulation pulses, for stimulating the pudendal nerve of the patient in order to cause muscle contraction to reduce patient incontinence, characterised in that the tampon electrode comprises a flexible electrically conductive outer sheath to facilitate conductance into the vaginal or anal wall of the patient.

The vaginal or anal tampon electrode may comprise a means for expanding and contracting the outer sheath to enhance conduction of the electrical stimulation pulses into the vaginal or anal wall of the patient by conforming the outer sheath to the vaginal or anal wall.

The vaginal or anal tampon electrode may comprise an indifferent skin surface electrode means.

The indifferent skin surface electrode may comprise a sheet electrode shaped for fitting to a sacral region of said patient, for stimulating nerves in the sacral region.

The sacral surface electrode means may comprise a sheet electrode having a shape of generally truncated triangle and which includes an apex plateau region and means, defining a dipped portion thereon, for facilitating finger placement of the sacral surface electrode over the sacral region.

The indifferent skin surface electrode may comprise a sheet electrode shaped for fitting to a perineal region of said patient, for providing stimulation to dorsal and perineal branches of the patient's pudendal nerve.

The perineal surface electrode may comprise a sheet electrode having an hourglass shape.

The indifferent skin surface electrode means may comprise a sheet electrode means applying a balanced pulse waveform positioned on a patient's sacral plexus, buttocks, abdomen or thigh.

The apparatus may comprise generator means for providing a series of electrical stimulation pulses having a form substantially as shown in Figure 23.

The generator may be adapted for providing a series of electrical stimulation pulses having a pulse train of bi-phasic pulses, with a modulated envelope having a duration in the range of 100 to 1,000 microseconds, with N pulses per envelope being provided, N being between 1 and 1,000. The generator may be adapted for providing the modulated envelope with a sequential, random or fixed frequency of between 0.1 and 100 Hz. The generator may be adapted for providing pulses in each envelope corresponding to a frequency of between 500 and 5,000 Hz.

Description of the Drawings

For a better understanding of the invention, and to show how the same may be carried into effect, reference will now be made, by way of example, to various specific embodiments of the invention as shown in the accompanying diagrammatic drawings, in which:

Figure 1 shows a portable drive module according to a specific embodiment of the present invention, for driving an electrode;

Figure 2 shows a schematic circuit diagram of the drive module;

Figure 3 shows in plan view a first cutaneous electrode pad according to a another specific embodiment of the present invention;

Figure 4 shows in plan view a second cutaneous electrode pad according to a further specific embodiment of the present invention;

Figure 5 shows in plan view a third cutaneous electrode pad in accordance with yet another embodiment of the present invention;

Figure 6 shows in plan view an electrode for positioning on the sacrum of a patient, according to another embodiment of the present invention;

Figure 7 shows an electrode for positioning in the perineal region, according to another embodiment of the present invention.

Figure 8 shows a construction of the embodiments of Figures 3 to 7;

Figure 9 shows one way of positioning the sacral electrode of Figure 6 on a patients skin;

Figure 10 shows one way of positioning the perineal electrode of Figure 7 on a patients skin;

Figures 11 to 19 show various prior art pulse geometry components;

Figure 20 shows part of one example of an electrical stimulation drive signal according to the present invention;

Figure 21 shows as an example according to the present invention, a part of an electrical stimulation drive signal in the form of a preprogrammed pulse train;

Figure 22 shows as an example according to the present invention, a part of an electrical stimulation drive signal having a bi-phasic pulse train envelope;

Figure 23 shows as an example according to the present invention, a form of an electrical stimulation drive signal having a bi-phasic pulse train and a pulse train envelope which is modulated;

Figures 24 to 26 show the preselected pulse geometry delivered in various pulse envelopes timed over predetermined exercise and relax periods. the voltage intensity in the initial and final time periods within each exercise and relax phase may also be ramped up or down for additional patient comfort.

Figures 24 shows as an example according to the present invention, a part of an electrical stimulation drive signal having uniform fixed rate envelopes;

Figure 25 shows as an example according to the present invention, a form of electrical stimulation drive signal having a randomly generated envelope;

Figure 26 shows as an example according to the present invention, a form of electrical stimulation drive signal having sequentially generated envelopes;

Figure 27 shows a first insertable electrode for internal use, according to an embodiment of the present invention;

Figure 28 shows a second insertable electrode according to another embodiment of the present invention;

Figure 29 shows a third insertable electrode according to another embodiment of the present invention;

Figure 30 shows a fourth insertable electrode according to another embodiment of the present invention;

Figure 31 shows a fifth insertable electrode according to another embodiment of the present invention.

Figure 32 shows a construction of part of an insertable electrode according to an embodiment of the present invention;

Figure 33 shows an inflatable electrode according to a specific embodiment of the present invention; and

Figure 34 shows a sensing apparatus according to a specific embodiment of the present invention.

Best Mode for Carrying out the Invention

An electro-stimulation apparatus according to a specific embodiment of the present invention comprises a drive module and a stimulation electrode arranged to be driven by the drive module.

Referring to Figures 1 and 2 of the accompanying drawings, a drive unit 1 comprises a portable case 2 which contains an electric battery power supply, 4, and electronics (not shown in Figure 1). The drive unit has a detachable instruction storage or programming means such as a smart card 3

and further comprises a clip for attaching the drive unit to an item of clothing, for example a belt.

The smart card 3 is attachable to the electronics of the drive unit 1 via a connection socket 5 and is detachable such that it can be replaced by a substitute Smart card.

The drive unit further features an intensity control 13 for controlling the intensity of the drive signal to the stimulator electrode, the intensity control being of a type which can be altered by the patient, and an indicator lamp 14 to indicate when the drive signal is operating and/or whether the battery is charged. A liquid crystal display (LCD) may also be provided to show the status of the device.

Referring to Figure 2 of the accompanying drawings, a schematic diagram of the electronics of the drive unit of Figure 1 is shown. The electronics comprises the socket 5 for accepting the Smart Card 3, a battery power supply 6 for supplying power to the electronics, a pulse generator 7, an output pulse shaper 8 for modifying the output of the pulse generator 7 and outputting a drive signal, a plurality of output sockets 9 connected to the output pulse shaper 8 and providing an output path for the drive signal, an intensity control 13, which is, for example a thumb wheel variable resistor, a real time logger 10 for recording parameters of the output of the pulse generator and/or drive signal and an external connector 11, for example a serial port through which the real time logger 10 can be interrogated periodically using separate interrogation equipment, for example a personal computer, and the battery charge/signal output indicator 14.

The output socket 9 is connectable to a stimulator electrode, which is driven by the drive signal via an output electrode lead 12 from the drive unit.

The electrode lead 12 is preferably of a high flex material such as silicon rubber, having standard 2mm plug pins or press-stud type fasteners for connecting to the stimulator electrode.

The Smart Card may be either pre-programmed or programmable using a standard PC. The smart card module could be replaced by some other instruction storage or programming means, e.g. an audio cassette, or an internal ROM programmable externally of the drive unit. Hereafter, for convenience, the instruction storage or programming means will be referred to as a Smart card.

In use, the drive module operates as follows. The pulse generator, produces a pulse signal in response to programmed instructions stored in the smart card 3. The pulse signal is then modified by the output pulse shaper 8 in accordance with the instructions stored in the Smart card. A drive signal appears at the output of the pulse shaper, on the output lead 12, and is supplied to the output socket 9 connected to the stimulation electrode.

Each smart card may be supplied either pre-programmed or programmable using a standard personal computer. Each pre-programmed smart card is clearly marked with the parameters of the drive signal which the card is programmed for producing, together with the type of therapeutic treatment to which these parameters relate. For example, a smart card may be marked with the following information, and programmed accordingly with

instructions for generating electrical stimulation drive signal having corresponding waveform characteristics.

Treatment, URINARY STRESS INCONTINENCE

Pulse geometry - square biphasic
Pulse width - 200 μsecs
Pulse envelope frequency - Random 5 - 40 Hz
Pulse envelope - 100 msecs
Exert/relax - 8 sec cycle 50% duty cycle
Treatment time - 2 hours
Intensity - 0 - 30 Ma.

In other Smart cards for other treatments, variations upon the above drive signal characteristics may be made. For example any of a number of drive signal characteristics may be varied.

The real time logger 10 records details of the pulse signal output from the pulse generator 7 through normal biological body impedance. Stimulation pulses generated during electrode disconnection or short circuit will not register on the data logger or Smart Card. Compliance of the output drive signal can be monitored and checked against treatment prescribed by a clinician. The recorded data shows whether a treatment has been administered on a regular basis, without any parameters of the drive signal being tampered with by the patient.

In use in a clinical situation, a complete electro-stimulator apparatus comprises a selection of stimulators, a selection of modules each programmed for a different type of treatment, treatment instruction cards corresponding

with the modules and giving instructions for the administration of treatment by the patient and/or clinician, a battery re-charger, (where required) and a full instruction guide on the use of the apparatus.

Figures 3 to 7 of the accompanying drawings show various embodiments of transcutaneous electrode pads suitable for perineal application. Such electrodes are suitable to be driven by the drive unit described with reference to Figures 1 and 2.

The electrode pads are constructed from woven or knitted electrically conductive cloth, mounted on a thin flexible and waterproof material and coated in a self-adhesive conductive gel. The conductive gel is of a known prior art type, and in one version is formulated to be adjustable in adhesive strength by the addition of water.

The first embodiment electrode 50 shown in Figure 3, a stud fastener 51 and a pigtail cable 52 having a socket 53 for connection to for example the output socket 9. Where a pigtail connection is used the conductive elements of the cable 52 may be extensions of the woven material of the electrode 50. Connection of the conductive elements to the plug 53 may be by moulding the elements into the plug, by sewing the elements into the plug after moulding, by adhesive bonding using a conductive adhesive or by ultrasonic welding. Similarly, the conductive elements of the cable 52 may be adhesively bonded to, or ultrasonically welded to, or sewn into the woven material of the electrode 50.

The electrode is shaped as shown, having an elongate strip 60 of a first width having projections 62 of a second width at each end. A perimeter 63 has one side 64 which is convex in shape, and one side 65 which is concave.

A preferred maximum length for the electrode shown in Figure 3 is of the order 50mm, and preferred widths are in the range 20 to 40mm, preferably in three sizes of widths 20mm, width 30mm and width 40mm.

Referring to Figure 4, a second embodiment electrode has a plug 51 or a pigtail 52, 53 similarly as above, and is of similar maximum dimensions as the first electrode.

A third embodiment electrode as shown in Figure 5, is of a "kidney" type shape, has either a plug 51 or pigtail 52, 53 and is preferably of external maximum dimensions of the same order as the electrode of Figure 13.

Although the above dimensions are preferred, it is anticipated that some variation in dimensions of up to plus or minus 100% may suit the wide variety of naturally occurring sizes and shapes of the perineal body.

Referring to Figure 6 of the accompanying drawings, an electrode suitable for fitting to the sacral region is shown. The electrode is of knitted or woven conductive cloth, similar to the above mentioned electrode, and is of a generally truncated triangular shape in plan view. The electrode has a base width of around 67mm, a height of around 70mm and a apex plateau region 200 of width around 15mm. The plateau region has a dipped portion for placement of a finger to aid in positioning of the electrode over the sacral spinous processes of S2, S3 and S4. The electrode is provided with a pigtail

electrical contact lead 201 of length around 54mm, terminating in a plug connector 202.

Referring to Figure 7 of the accompanying drawings a surface electrode 203 suitable for fitting to the perineal region comprises a sheet of conductive woven or knitted material in the shape of an hour glass 205, having a length of around 50mm and a width of around 40mm. The neck of the hour glass shaped electrode is preferably of width around 16mm, and a pigtail lead of length around 92mm is provided. Preferably, the pigtail lead is attached at the side of the electrode as shown in Figure 7, for hygiene and ease of fitting.

Referring to Figure 8, a structure of an electrode pad is shown. The pad comprises a woven or knitted conductive cloth 80, coated in a conductive adhesive gel 81. The adhesive gel may be of a known type. The cloth 80 is coated by a water proof backing 82, which is for example a plastics sheet material. The water proof backing is attached to the cloth by an adhesive layer 83. A conducting wire 84, in the form of a pigtail lead is electrically and physically attached to the cloth 80. A drive signal is transmitted along the pigtail to drive the electrode. The electrode pad has a press-stud 85, which may be used for aiding placement of the pad using a strap or the like. The stud may be electrically conducting and contact the cloth 80 such that a drive signal may be supplied via the stud in addition to or in alternative to the pigtail lead 84.

Referring to Figure 9 of the accompanying drawings, placement of the sacral surface electrode of Figure 8 is shown schematically, in combination with a further surface electrode 300 placed on a buttock of the patient, the further electrode being an indifferent electrode.

Preferably the sacral surface electrode is positioned over the sacral spine S2 - S4. Placement of the indifferent electrode is optional.

Referring to Figure 10 of the accompanying drawings, the perineal surface electrode as described with reference to Figure 8, is shown positioned over the perineal body of a patient to provide stimulation to the dorsal and perineal branches of the pudendal nerve 301. The sacral electrode 302 is also shown in position.

Any of the above electrodes may be reusable or disposable.

Use of the apparatus described with reference to Figures 1 to 10 will now be described, referring also to Figures 11 to 26.

In use, for treating urinary incontinence, one or more of the above electrodes are deployed over a perineal body between (in a female) the vagina and the anus. It is important that the electrode remains firmly in position during normal movement and is flexible enough to accommodate such movement. The use of a knitted or woven conductive material with a conductive adhesive gel in an electrode of shape specifically adapted for the perineal region may provide the necessary comfort and secure fixing to allow treatment of incontinence by a cutaneous electrode to be acceptable to the patient.

The electrical stimulation drive signal may be constructed as a combination of one or more signal per pulse geometries. Examples of such signal pulse geometries which may be selected according to instructions on the smart card are shown in Figures 11 to 19. For example Figure 11 shows a

simple Galvanic type waveform. Figure 12 shows a simple sinusoidal waveform. Figure 13 shows a square monophasic waveform. Figure 14 shows a square waveform. Figure 15 shows a square bi-phasic waveform. Figure 16 shows a pulsatile (asymmetric balanced) waveform. Figure 17 shows a Faradic waveform. Figure 18 shows a monophasic sawtooth spike waveform, and Figure 19 shows a bi-phasic sawtooth spike, waveform.

The Pulse Width may be selectable from, for example, any one of 80, 160, 200, or 320 μsec widths. The Pulse Envelope frequency may be selected from any one of three types. Type one is a regular fixed frequency rate, for example 10Hz. Type two is a sequential rate rising or falling from a preset starting frequency to a preset final frequency. Type three is a randomly generated frequency rate with pulse separations occurring randomly between preset start and end frequencies. The pulse envelope duration may be selected from a range including for example 100, 250, 500, 750, or 1,000 μsecs. The Exercise/Relax cycle is similarly variable and the initial and final intensity voltages may be adjustable to provide a smooth ramp up and down for patient comfort. The overall treatment time is variable and the intensity may be selectable from the following ranges: 0 - 30mA, 0 - 60 mA, or 0 - 100mA.

Referring to Figure 20 of the accompanying drawing, an example of a portion of a specific output drive signal waveform in accordance with specific pre-programmed instructions is shown. The example shown comprises a square monophasic waveform having a pulse burst duration of 100 μsecs and a frequency of 2 Khz. The pulse width is 80 μsecs and the period between bursts is 99 ms. The intensity (the height of the pulse in Figure 11) is adjustable by the patient in the range 0 - 60mA. Other portions

of the drive signal waveform may have a frequency in the range 1Hz to 2KHz.

Referring to Figure 21 of the accompanying drawings, a typical preprogrammed bi-phasic pulse train is shown. The pulse train comprises a first pulse 500 of duration time T1, an inactive period 501 of duration time T2, a second pulse 503, of an opposite sense to the first pulse 500, and of duration time T3, and a second inactive time T4, the second inactive time being variable according to the frequency selected. The times T1, T2 or T3 are variable but typically may be T1=200 μsecs, T2=100 μsecs, T3=200 μsecs.

Referring to Figure 22, a preferred form of bi-phasic pulse is shown in an envelope train. The envelope duration is preferably in the range 100 to 1,000μsecs, and N pulses per envelope are provided, N preferably being in the range 1 to 1,000. The envelope frequency FR2 can be sequential, random or fixed and is typically in the range 0.1 to 100Hz. The period between repetitions of pulse packets, FR1 typically corresponds to a frequency of 500 to 5,000Hz.

Referring to Figure 23, a pulse train having a modulated envelope is shown. The modulation of the pulse train envelope can be any suitable shape. The duty cycle of the envelope, within the envelope period defined by the envelope frequency FR2, is preferably in the range 1 to 99%.

Referring to Figure 24 of the accompany drawings, an example of a uniform (fixed) rate envelope is shown. A preselected pulse geometry of pulses being spaced apart by 2 μsecs, with a preselected pulse geometry of

either a monophasic or bi-phasic, and either a square or random characteristic is selected.

Figure 25 shows a random generated envelope sequence in which pulses within the envelope are randomly spaced apart from each other, in this example by a period between a first and second pulse being 2 μsecs, the period between the second and third pulse being randomly selected as 10 μsecs, the period between the third and fourth pulse being randomly selected as 6 μsecs, between the fourth and fifth pulse the time is randomly selected as 2 μsecs, and between the fifth and sixth pulse the time is randomly selected as 4 μsecs. In a succeeding pulse envelope, the times between the pulses within the envelope are randomly selected again, and are different from those in the first envelope shown.

Use of a randomly generated pulse train within a fixed pulse envelope may have an advantage that the human body does not become acclimatised to the particular form of treatment. The patients body may maintain its response to the treatment, which has no predictable pulse pattern within the pulse envelope, over an indefinite period, without significant loss of effectiveness.

Referring to Figure 26 of the accompanying drawings, a set of sequentially generated envelopes are shown in which the exercise phase (i.e. the period occupied by the pulse envelope), and the relax phase are variable. This is equivalent to varying the position in time of the pulse envelope within the duty cycle. In the example shown, within the pulse envelope, the pulses are ordered such that the second pulse is spaced from the first pulse by a time of 2 μsecs, the time elapsed between the second and third pulses is 4 μsecs, the time elapsed between the third and fourth pulses is 6 μsecs, and the time

elapsed between the fourth and fifth pulses is 8 μsecs. This pattern is repeated in successive sequentially generated envelopes.

Hereinabove, Figures 24 to 26 have shown the exercise/relax cycles with a constant amplitude at start and finish. This may be replaced with a gradual ramp up/down over a preselected period similar to that shown in Figure 24.

Various other electrodes, of the insertable type, will now be described.

Referring to Figure 27 of the accompanying drawings, a first insertable electrode comprises an inner core moulded from a resilient and deformable material such as a foam, or paper/cotton fibre 100 and an outer conductive sheath 101 of knitted or woven conductive fibre, for example stainless steel fibre, or metallized plastic fibre. The outer conductive sheath surrounds the inner core 100. Individual fibres of the outer conductive sheath are gathered into a thread 102 and connected via a crimp connection 103 to a flexible pigtail connector wire 104 of, for example, silicon rubber coated wire. The flexible pigtail connector wire has at one end a plug 105 for connection to a drive unit.

The material of the inner core 100 and the outer conductive sheath 101 are deformable to allow compression and insertion of the electrode into a hollow tubular applicator (not shown). A suitable core material has a Shore hardness of below 45, and is deformable enough so as to be compressed to 75% or less of its unrestricted size. In an electrode of dimensions suitable for insertion into a vaginal or rectal tract, a surface of the foam is preferably depressible by at least 1.5mm.

Biocompatible fibres may be used in the construction. For example Biocompatible Polyvinyl Formal (PVF) foam, cotton or paper materials.

The electrode may be manufactured as a single moulded flexible conductive foam or as a moulded PVF foam plug surround by flexible conductive woven or knitted cloth sheath. In this latter embodiment, the sheath may be incorporated during the moulding phase of manufacture or may be fitted after moulding.

The electrode may alternatively be manufactured as a moulded PVF foam as above, but with an inner plug manufactured from fibrous paper or cotton material.

In use, the applicator, containing the electrode, is inserted into either a vaginal or anal tract, to position the electrode therein. The applicator is then withdrawn, without moving the electrode. Once released, the foam material of the electrode expands to provide close contact with an internal wall of the vaginal or anal tract. A lubricating gel may be used during insertion and/or extrusion of the applicator to aid deployment. The gel may be conductive.

The electrode may be washable or disposable.

Referring to Figure 28, a second insertable electrode comprises an elongate substantially cylindrical core of a resilient deformable material 100 as aforementioned with reference to Figure 27, having a tubular band of conductive material 101 which surrounds and constricts a mid portion 109 of the core. At either end of the band, portions of the core 110, 111, which are

unrestrained by the band 101 relax to adopt an un-compressed diameter greater than the diameter of the constricted mid portion of the core 109.

The mid portion 109 of the core may be further compressible by compressing the conductive material 191, but is restricted from substantial expansion to a fully relaxed state by the band 101.

The tubular band is of length in the range 15 to 20mm, the overall length of the core being suitably in the range 50 to 60mm and the relaxed diameter of the core being in the range 20 to 30mm. These dimensions may be varied to accommodate natural anatomical variations.

The second electrode has an hollow tubular passage 108 centrally, for accommodating a rigid rod centrally in the core. Using this rod, the electrode may be pushed into the tract without the need for an enclosing applicator as described with reference to Figure 18. In this mode of deployment, the end portions 110, 111 of the core, and/or the mid portion 109 may be squeezed during insertion, and then expand when in place in the tract.

However, the embodiment is not restricted to this mode of deployment and may be inserted in a hollow applicator as aforementioned with reference to Figure 18, and may retained in the tract during removal of the applicator by the insertion of the rod in the hollow passage 108. The rod is subsequently removed.

The second insertable electrode has a contact lead 104 and plug 105 for making electrical connection to the conductive material 101 and for use in removing the electrode from the tract.

Referring to Figure 29, a third insertable electrode is of similar construction to the second electrode, but, a tubular band 130 of conductive material of length in the range 6 to 12mm is provided.

Referring to Figure 30, a fourth insertable electrode is of similar construction to the above mentioned first insertable electrode, of Figure 18, however, in the fourth insertable electrode, a hollow passage 108 is provided in the core 131 for insertion of a rigid rod, similarly as described with reference to the second insertable electrode.

Referring to Figure 31, a fifth insertable electrode comprises a core of flexible material 100, similarly as described with reference to Figure 19, and first and second tubular bands 150, 151 each of a conductive material as described hereinabove with reference to Figures 18 to 21. Each conductive band 150, 151 is connected to a respective first and second conductor leads 152, 153, in a manner as hereinabove described.

Preferably, the conductive bands are each of length 6mm or thereabouts, and separated by a distance of 8mm, although these dimensions and lay outs are not restrictive and may be varied. During treatment, the inflatable tampon electrode may be used periodically to monitor progress and provide encouragement for the patient to continue.

The fifth electrode may be deployed as previously described hereinabove with reference to Figure 28.

In use, the fifth electrode may be electrically driven via the first and second leads 152, 153 by respective first and second drive signals. The first

and second drive signals need not be identical, and preferably have different parameters. Such an electrode may be suitably useable in FES treatment.

Referring to Figure 32, a structural portion of an insertable electrode is shown. Such a structure may be incorporated into any one or more of the insertable electrodes as described with reference to Figures 27 to 31 as hereinabove described.

The structure comprises a core of foam material 100, such as hereinabove described, an electrically insulating backing material 140, for example a sheet material, an adhesive layer 141, and a conductive fibre material 142. The insulating backing material and adhesive layer are sandwiched between the conductive material and the core.

A connecting lead 143, in the form of a pigtail wire, is incorporated into the structure, making electrical contact with the conductive material 142. The connection is of sufficient strength to enable the insulating electrode to be pulled using the connecting lead, without the connecting lead coming loose from the structure. Additionally, the lead may be woven into or otherwise attached to the conductive fibre 142, similarly as herein described with reference to cutaneous electrodes.

Referring to Figure 33 of the accompanying drawings, an inflatable tampon electrode for insertion into the vagina or anus of a patient is shown, the electrode having an outer sheath 600, of a rubber silicon material, the outer sheath being inflatable or deflatable by air which is pumped in through a delivery pipe 601 and a rigid internal member 602, and a woven or knitted conductive cloth 603 bonded to the outer surface of the rubber sheath 600.

The conductive sheath is connected to external sensing apparatus by an electrically conductive lead wire 604 which runs through the centre of the rigid member and the hollow air delivery pipe 601.

Referring to Figure 34 of the accompanying drawings, the other end of the delivery pipe 601 and connecting lead 604 enter a sensing apparatus 700. The sensing apparatus comprises a pressure sensor 701, a pulse generator 702, an electromyographic sensor 703, an air compressor 704, and a display and data recorder 705.

The tampon electrode of Figure 35 and the sensing apparatus of Figure 34 are used in various modes as follows. Firstly, the air compressor is run continuously to inflate the inflatable tampon electrode of Figure 35. A patient is encourage to squeeze the tampon electrode, and changes in air pressure are detected by the pressure sensor 701 and displayed by the display and data recorder 705. Thus a measure of the strength of a patient's muscles can be determined by the read out on the display and data recorder 705. Alternatively, the patient can be asked to squeeze the electrode, and the number of strokes of the air compressor counted in order to reach a predetermined pressure. This number of strokes will also give a measure of the condition of the patient's muscles.

In a facilitation mode, the patient is encouraged to squeeze the electrode, which is inflated by the air compressor 70, when squeezing of the electrode is detected by either a pressure difference monitored by the pressure sensor 701, or by a difference in the amount of work the air compressor needs to do to keep the electrode inflated, then the pulse generator generates a signal in response to either of these two detected parameters and transmits this along

the conductive lead 604 to electrically stimulate the muscles. This results in further contraction, aiding the patient in their squeezing action. Additionally, the pulse generator may be activated in response to an output from the electromyographic or perineometer sensor 703.

Any one or more of the above described internal electrodes can be used to perform Pelvic Floor Exercises. The preferred method is by using the embodiment of Figure 33 in conjunction with Bio feedback and Facilitated Electrical Stimulation. In such exercise, a (female) patient, practices squeezing exercises by squeezing and relaxing against the resilience of the electrode.

The patient exercises by working muscles against the resilience of the core material, rather than by attempting to keep the core in situ.

Variations in the resilience and deformability of the core material 100 may be made to suit various exercises. A series of electrodes may be provided, each electrode being of a progressively increased deformability and/or resilience to provide a means of performing a programme of progressively more advanced exercises.

In the above described embodiments of insertable electrodes, the outer conductive sheath may be completely conductive over the whole of its surface, or may comprise one, two or more conductive bands incorporated therein. In either case, the conductive material contacts the wall of the tract to deliver an electrical signal thereto. The sheath may be constructed from flexible woven or knitted cloth or may be of stitched construction using conductive fibres. The sheath may be sewn or bonded to the core.

In each embodiment of the internal electrode, the connecting pigtail wires are preferably sewn or crimped to the sheath to be used for pulling the electrode during removal from the cavity.

A main advantageous feature of the various of the above embodiments may be an ability to multiplex facets an individual patient's treatment programme. For example, in Stress incontinence, the patient may follow a particular set of preset instructions for NTS treatment which would be intended to restore a pudendal nerve function and regenerate type I slow muscle fibres.

The treatment can be applied via a cutaneous perineal electrode and an arbitory indifferent electrode positioned on the buttock, thigh or abdomen, with the treatment pulse preset to a specified set of parameters by the smart card selected for this aspect of treatment.

In later weeks the treatment may require that the type I slow fibres require additional strengthening and the electrode system could then be changed for NMS treatment, by passing the pulse between the single banded tampon electrode and either a cutaneous perineal or arbitory indifferent electrode. The electrical parameters for the electrode drive signals could be provided in accordance with appropriate instructions contained in a second smart card.

At the end of the treatment, it may then be preferable to add to the strength of the type II fast fibres which may best be achieved by FES treatment, applied using a single double banded tampon electrode driven by

a new selected drive signal in accordance with new instructions contained in a third smart card.

The final part of the treatment may include use of the bio-feedback facility.

Thus, a flexible treatment apparatus and system may be provided, using a single piece of equipment. In contrast, using prior art systems, a patient would possibly only receive one of the aforementioned modes of treatment, or alternatively, three separate sets of equipment would be necessary.

Specific embodiments of the invention may have an advantage of providing variable combinations of pulse geometry, intensity ceilings and preset treatment parameters to suit, in addition to urinary or faecal incontinence treatment, therapeutic requirements including Transcutaneous Electrical Nerve Stimulation (TENS), Functional Electrical Stimulation (FES), Neuro Muscular Stimulation (NMS), Neuro Trophic Stimulation (NTS), Interferential Therapy, Iontophoresis or Galvanism.

Specific embodiments of the invention may provide a versatile apparatus which provides a combination of electro-stimulation treatments available in a single unit. The module may have an advantage of being easily set by a clinician to provide a prescribed electro-stimulation treatment, yet be tamper proof by a patient.

Various of the embodiments may have an advantage of being capable of recording details of the administration of a prescribed treatment such that

a clinician can periodically monitor such administration when the patient is out of clinic.

The embodiments may advantageously provide an electro-stimulation apparatus which is portable by a patient, and can be preset to provide a drive signal having fixed parameters selected from a range of selectable drive signal parameters.

Specific embodiments of the present invention may have an advantage of providing means of treatment for incontinence using a flexible sheet material electrode.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature

disclosed is one example only of a generic series of equivalent or similar features.

CLAIMS

1. Apparatus for application of electrical stimulation to patients suffering from incontinence, said apparatus comprising:

generator for providing a series of electrical stimulation pulses; and

a tampon electrode means, responsive to said series of electrical stimulation pulses, for stimulating the pudendal nerve of the patient in order to cause muscle contraction to reduce patient incontinence, characterised in that the tampon electrode comprises a flexible electrically conductive outer sheath to facilitate conductance into the vaginal or anal wall of the patient.

2. The apparatus according to claim 1, wherein said vaginal or anal tampon electrode further comprises a means for expanding and contracting the outer sheath to enhance conduction of the electrical stimulation pulses into the vaginal or anal wall of the patient by conforming the outer sheath to the vaginal or anal wall.

3. The apparatus according to claim 1 to 2, wherein said vaginal or anal tampon electrode means further comprises an indifferent skin surface electrode means.

4. The apparatus according to claim 3, wherein said indifferent skin surface electrode comprises a sheet electrode shaped for fitting to a sacral region of said patient, for stimulating nerves in the sacral region.

5. The apparatus according to claim 4, wherein said sacral surface electrode means comprises a sheet electrode having a shape of generally truncated triangle and which includes an apex plateau region and means, defining a dipped portion thereon, for facilitating finger placement of the sacral surface electrode over the sacral region.

6. The apparatus according to claim 3, wherein said indifferent skin surface electrode means comprises a sheet electrode shaped for fitting to a perineal region of said patient, for providing stimulation to dorsal and perineal branches of the patient's pudendal nerve.

7. The apparatus according to claim 6, wherein said perineal surface electrode means comprises a sheet electrode having an hourglass shape.

8. The apparatus according to claim 3, wherein said indifferent skin surface electrode means comprises a sheet electrode means applying a balanced pulse waveform positioned on a patient's sacral plexus, buttocks, abdomen or thigh.

9. Apparatus according to any one of claims 1 to 8, for application of electrical stimulation to patients suffering from incontinence, said apparatus comprising generator means for providing a series of electrical stimulation pulses having a form substantially as shown in Figure 23.

10. Apparatus according to claim 9 wherein the generator is adapted for providing a series of electrical stimulation pulses having a pulse train of bi-phasic pulses, with a modulated envelope having a duration in the range of

100 to 1,000 microseconds, with N pulses per envelope being provided, N being between 1 and 1,000.

11. The apparatus according to claim 10 wherein the generator is adapted for providing the modulated envelope with a sequential, random or fixed frequency of between 0.1 and 100 Hz.

12. The apparatus according to claim 11 wherein the generator is adapted for providing pulses in each envelope corresponding to a frequency of between 500 and 5,000 Hz.

13. Apparatus for application of electrical stimulation to patients substantially as hereinbefore described with reference to Figures 27 to 34 of the accompanying drawings.

Amendments to the claims have been filed as follows

1. Apparatus for application of electrical stimulation to patients suffering from incontinence, said apparatus comprising:

generator for providing a series of electrical stimulation pulses; and

a tampon electrode means, responsive to said series of electrical stimulation pulses, for stimulating the pudendal nerve of the patient in order to cause muscle contraction to reduce patient incontinence, characterised in that the tampon electrode comprises a band or sheath made of flexible, electrically conductive material comprising conductive fibres to facilitate conductance into the vaginal or anal wall of the patient.

2. The apparatus according to claim 1, wherein said vaginal or anal tampon electrode further comprises a means for expanding and contracting the conductive sheath to enhance conduction of the electrical stimulation pulses into the vaginal or anal wall of the patient by conforming the conductive sheath to the vaginal or anal wall.

3. The apparatus according to claim 1 or 2, wherein said tampon electrode means comprises a core which is at least partially surrounded by said band or sheath.

4. The apparatus according to claim 3, wherein said core comprises a resilient and deformable material.

5. The apparatus according to any preceding claim, wherein said band or sheath comprises knitted or woven conductive fibres.

6. The apparatus according to any of claims 1 to 4, wherein said band or sheath comprises a stitched construction using conductive fibres.

7. The apparatus according to any preceding claim, wherein the conductive fibres comprise stainless steel fibres.

8. The apparatus according to any of claims 1 to 6, wherein the conductive fibres comprise metallized plastic fibres.

9. The apparatus according to claim 3 or any claim dependent thereon, wherein an electrically insulating backing material and/or an adhesive layer are provided between said band or sheath and said core.

10. The apparatus according to any preceding claim, wherein said apparatus further comprises an indifferent skin surface electrode means.

11. The apparatus according to claim 10, wherein said indifferent skin surface electrode comprises a sheet electrode shaped for fitting to a sacral region of said patient, for stimulating nerves in the sacral region.

12. The apparatus according to claim 11, wherein said sacral surface electrode means comprises a sheet electrode having a shape of generally truncated triangle and which includes an apex plateau region and means, defining a dipped portion thereon, for facilitating finger placement of the sacral surface electrode over the sacral region.

13. The apparatus according to claim 10, wherein said indifferent skin surface electrode means comprises a sheet electrode shaped for fitting to a

perineal region of said patient, for providing stimulation to dorsal and perineal branches of the patient's pudendal nerve.

14. The apparatus according to claim 13, wherein said perineal surface electrode means comprises a sheet electrode having an hourglass shape.

15. The apparatus according to claim 10, wherein said indifferent skin surface electrode means comprises a sheet electrode means applying a balanced pulse waveform positioned on a patient's sacral plexus, buttocks, abdomen or thigh.

16. Apparatus according to any preceding claim, for application of electrical stimulation to patients suffering from incontinence, said apparatus comprising generator means for providing a series of electrical stimulation pulses having a form substantially as shown in Figure 23.

17. Apparatus according to claim 16, wherein the generator is adapted for providing a series of electrical stimulation pulses having a pulse train of bi-phasic pulses, with a modulated envelope having a duration in the range of 100 to 1,000 microseconds, with N pulses per envelope being provided, N being between 1 and 1,000.

18. The apparatus according to claim 17, wherein the generator is adapted for providing the modulated envelope with a sequential, random or fixed frequency of between 0.1 and 100 Hz.

19. The apparatus according to claim 18, wherein the generator is adapted for providing pulses in each envelope corresponding to a frequency of between 500 and 5,000 Hz.

20. Apparatus for application of electrical stimulation to patients substantially as hereinbefore described with reference to Figures 27 to 34 of the accompanying drawings.

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The Patent Office

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Application No: GB 9616613.7
Claims searched: 1-13

Examiner: David Brunt
Date of search: 13 September 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RHEPV)

Int Cl (Ed.6): A61N (1/05)

Other: Online: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 1480103	(GARBE) whole document	1
X	EP 0411632 A1	(EMPI) see column 2 lines 13-34 and column 3 lines 6-10	1,2
X,P	US 5117840	(BRENMAN) see column 5 lines 63-64 and column 6 lines 48-49	1
X	US 4873996	(MAURER) see column 2 line 57 to column 3 line 20	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.